

## **Section 5 - 510(k) Summary**

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<b>Date Prepared:</b>	May 15, 2015		
<b>Trade Name:</b>	DG Gel 8 Neutral		
<b>Classification:</b>	Class II Automated Blood Grouping and Antibody Test System 21 CFR 864.9175		
<b>Product Code:</b>	KSZ		
<b>Predicate Device:</b>	Diagnostic Grifols S.A. believes that use of the DG Gel 8 Neutral as a control card for Blood Grouping Reagents is substantially equivalent to the cleared DG Gel 8 Neutral card (Classification Number: 864.9175, Product Code: KSZ).		
<b>Device Description:</b>	<p>DG Gel 8 Neutral card consists of a plastic support with eight microtubes containing gel in a buffered medium.</p> <p>The microtubes, without antibodies, are used in techniques where antibodies react directly with the red blood cells.</p> <p>The use of the DG Gel 8 Neutral card as a control card should be performed in parallel with the Blood Grouping Reagent DG Gel 8 cards, according to the method detailed in the package insert of the products being controlled. The expected result for the control microtube should be negative. A positive result may be due to potent cold or warm autoantibodies, to spontaneous agglutination, to intense rouleaux formation, or other causes. If the control microtube is positive the results of the test cannot be correctly interpreted.</p> <p>Although there are limitations of the ability of the control to detect false positive agglutinations due to many variables including the amount of antibody bound to the red blood cells, the temperature range of the interfering antibody, and its immunoglobulin subclass, most of the widely accepted transfusion standards and practices require running a control along with the ABO type and Rh determination.</p>		
<b>Indications For Use:</b>	<p>The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube.</p> <p>For use with the DG Gel System.</p> <p>For <i>in vitro</i> diagnostic use.</p>		
<b>Functional and Safety Testing:</b>	Not Applicable.		
<b>Substantial Equivalence Similarities:</b>	<b>Parameter</b>	<b>Subject Device New Use of DG Gel 8 Neutral card</b>	<b>Predicate device Cleared DG Gel 8 Neutral card</b>
	Principle of the test	The test is based on the immunohematology gel technique described by Yves Lapierre.	SAME
	Classification	Class II; 21 CFR 864.9175	SAME
	Product Code	KSZ	SAME

	Common Name	Automated Blood Grouping and Test Systems	SAME
	Results	Report results as an agglutination grade, absence of agglutination or hemolysis.	SAME
	Composition	Gel in buffered medium with sodium azide as a preservative.	SAME
	Storage conditions	2-25°C	SAME
	Reagent preparation	The gel card is provided ready to use.	SAME
	Number of microtubes	8	SAME
	Techniques	Saline techniques: <ul style="list-style-type: none"> <li>- Determination of the ABO reverse group</li> <li>- ABO compatibility test (immediate spin crossmatch test)</li> <li>- Antibody detection (at cold, room temperature and 37°C)</li> </ul> Enzymatic techniques <ul style="list-style-type: none"> <li>- Screening and/or identification of unexpected antibodies.</li> </ul>	SAME
<b>Substantial Equivalence Differences:</b>	Parameter	<b>Subject Device</b> <b>New Use of DG Gel 8 Neutral card</b>	<b>Predicate device</b> <b>Cleared DG Gel 8 Neutral card</b>
	Intended Use	The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube. For use with the DG Gel System. For in vitro diagnostic use.	The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples. For use with the DG Gel System. For in vitro diagnostic use.
	Technique	Saline techniques: <ul style="list-style-type: none"> <li>- Use as a Control microtube.</li> </ul>	Does not include the use as a control microtube
<b>Performance:</b>	No specific clinical studies were performed in support of the extended use of the DG Gel 8 Neutral card as control card. This use was already tested in the Clinical Studies DG001, DG002, DG003 and DG004 because the DG Gel 8 ABO/Rh + Kell card already includes a microtube with no antibodies for control purposes. The formulation of the gel used in the control microtube from the DG Gel 8 ABO/Rh + Kell is identical to the formulation of the gel used in the microtubes of the DG Gel 8 Neutral card. These four Clinical Studies were conducted by Diagnostic Grifols, S.A. to support the licensure of its DG Gel 8 reagents and the 510k clearance of the DG Gel instruments (Erytra, WADiana Compact, DG Reader, DG Spin and DG Therm), the DG Gel 8 Neutral card and the Grifols Diluent.		
<b>Conclusion:</b>	Grifols concludes, based on all information submitted and discussed in this submission and in this summary that the use of the DG Gel 8 Neutral as a control card for the Blood Grouping Reagents is substantially equivalent to the predicate device and has been demonstrated that the DG Gel 8 Neutral card including this new intended use is safe and effective.		